DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; The REDS-II Donor Iron Study: Predicting Hemoglobin Deferral and Development of Iron Depletion in Blood Donors

Summary: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Heart, Lung , and Blood Institute (NHLBI), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on August 28, 2006, pages 50925–50926 and allowed 60-days for public comment. No comments were received in response to this notice. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a current valid OMB control number.

Proposed Collection: Title: The REDS-II Donor Iron Study: Predicting Hemoglobin Deferral and Development of Iron Depletion in Blood Donors. *Type of Information Collection Request:* NEW. *Need and Use of Information Collection:* Although the overall health significance of iron depletion in blood donors is uncertain, iron depletion leading to iron deficient erythropoiesis and lowered hemoglobin levels results in donor deferral and, occasionally, in mild iron deficiency anemia. Hemoglobin deferrals represent more than half of all donor deferral, deferring 16% of women. Several cross sectional studies of blood donors, using older measures of iron status in blood donors have indicated that female sex, frequent donation and not taking iron supplements are predictors of iron depletion. However, none of these studies have included racial/ethnic, anthropomorphic, or behavioral factors and none have evaluated the impact of newly discovered iron protein polymorphisms. The REDS-II Donor Iron Study is a longitudinal study of iron status in two cohorts of blood donors: a first time/reactivated donor cohort in which baseline iron and hemoglobin status can be assessed without the influence of previous donations, and a frequent donor cohort, where the cumulative effect of additional frequent blood donations can be assessed. Each cohort's donors will donate blood and provide evaluation samples during the study period. We also propose to assess the baseline status of a group of first-time donors who are deferred for low hemoglobin on their first visit.

The primary goal of the study is to evaluate the effects of blood donation intensity on iron and hemoglobin status and assess how these are modified as a function of baseline iron/hemoglobin measures, demographic factors, and reproductive and behavioral factors. Hemoglobin levels, a panel of iron protein, red cell and reticulocyte indices will be measured at baseline and at a final follow-up visit 15–24 months after the baseline visit. A DNA sample will be obtained once at the baseline visit to assess three key iron protein polymorphisms. Donors will also complete a self-administered survey assessing past blood donation, smoking history, use of vitamin/mineral supplements, iron supplements, aspirin, frequency of heme rich food intake, and, for females, menstrual status and pregnancy history at these two time points. This study aims to identify the optimal laboratory measures that would predict the development of iron depletion, hemoglobin deferral, and/or iron deficient hemoglobin deferral in active whole blood and double red cell donors at subsequent blood donations. The data collected will help evaluate hemoglobin distributions in the blood donor population (eligible and deferred donors) and compare them with NHANES data. Other secondary objectives include elucidating key genetic influences on hemoglobin levels and iron status in a donor population as a function of donation history; and establishing a serum and DNA archive to evaluate the potential utility of future iron studies and genetic polymorphisms.

This study will develop better predictive models for iron depletion and hemoglobin deferral (with or without iron deficiency) in blood donors; allow for the development of improved donor screening strategies and open the possibility for customized donation frequency guidelines for individuals or classes of donors; provide important baseline information for the design of targeted iron supplementation strategies in blood donors, and improved counseling messages to blood donors regarding diet or supplements; and by elucidating the effect of genetic iron protein polymorphisms on the development of iron depletion, enhance the understanding of the role of these proteins in states of iron stress, using frequent blood donation as a model. *Frequency of Response:* Twice. *Affected Public:* Individuals. *Type of Respondents:* Adult Blood Donors. The annual reporting burden is a follows: *Estimated Number of Respondents:* Baseline visit: 4,290, Follow up Visit: 2,040; *Estimated Number of Responses per Respondent:* 1; *Average Burden of Hours per Response:* Baseline Visit: 0.12, Follow up Visit: 0.1; and *Estimated Total Annual Burden Hours Requested:* Baseline visit: 515, Follow up Visit: 204. The annualized cost to respondents is estimated at: Baseline Visit: $9,270, Follow up Visit: $3,672 (based on $18 per hour). There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

TABLE A.12.—ESTIMATES OF HOUR BURDEN AND ANNUALIZED COST TO RESPONDENTS

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Hourly wage rate ($)	Estimated total annual burden hours requested
Blood donors at Baseline Visit	4,290	1	0.12	18	515
Blood donors at Follow-up Visit	2,040	1	0.1	18	204
Total					719

Request for Comments: Written comments and/or suggestions from the public and affected agencies should address one or more of the following points: (1) Whether the proposed collection of information is necessary